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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,762	03/19/2001	Virginia Goss Tusher	M-10523 US	8102

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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/811,762	TUSHER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22, 28-30, 33, 44, 46, 58, 60, 65 and 66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22, 28-30, 33, 44, 46, 58, 60, 65, and 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicants' response, filed 2 February 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 23-27, 31, 32, 34-43, 45, 47-57, 59, and 61-64 have been cancelled. Claims 1-22, 28-30, 33, 44, 46, 58, 60, 65, and 66 are currently pending.

#### **Claim Rejections - 35 USC § 101**

##### ***Non-Statutory Subject Matter***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-22, 28-30, 33, 44, 46, 58, 60 remain rejected under 35 U.S.C. 101 and new claims 65 and 66 are rejected as necessitated by amendment because the claimed invention is directed to non-statutory subject matter, for the reasons set forth in the previous Office Action and expanded upon below.

The computer-implemented method, storage device, and system of the instant claims is directed to analyzing a plurality of values (data) by providing parameters, adjusting parameters, deriving observed versus expected values and comparing the values to produce a list. The claims do not produce a result which is concrete, tangible, and useful. The claims merely encompass combinations of groups of data about statistical differences in mRNA or protein levels, with no specific output that meets the concrete, tangible, and useful criteria. The claims use unspecified

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data of unspecified parameters. No specific outcome is set forth in the claims such that the steps of the method produce a result that is immediately concrete, tangible, and useful. The claims must, as a whole, satisfy section 101 and must be for practical application, which can be defined as:

1. The claimed invention “transforms” and article or physical object to a different state or thing.

*[The claimed invention in the instant case does not transform any physical object or article]*

2. The claimed invention otherwise produces a useful, concrete, and tangible result, based upon various factors (see below) *[The claimed invention in the instant application does not produce a concrete, tangible, and useful result]*.

#### Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation “is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application.” AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452... In determining whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete.” (1) “USEFUL RESULT” For an invention to be “useful” it must satisfy the utility requirement of section 101. The USPTO’s official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP § 2107 and Fisher, 421 F.3d at \_\_\_, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of “specific” and “substantial”). (2) “TANGIBLE RESULT” The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had “no substantial practical application.”). “[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection.” Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 (“It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .”). In other words, the opposite meaning of “tangible” is “abstract.” (3) “CONCRETE RESULT” Another consideration is whether the invention produces a “concrete” result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In re Swartz, 232 F.3d 862, 864, 56 USPQ2d

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1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is “irreproducible” claim should be rejected under section 101). The opposite of “concrete” is unrepeatable or unpredictable.

**Descriptive** material can be characterized as either “functional descriptive material” or “nonfunctional descriptive material”. In this context, “functional descriptive material” consists of data structures and computer programs which impart functionality when employed as a computer component (The definition of “data structure” is “a physical or logical relationship among elements. Designed to support specific data manipulation functions.” The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5<sup>th</sup> ed. 1993)). “Nonfunctional descriptive material” includes, but is not limited to, music, literary works and a compilation or mere arrangement of data.

Both types of “descriptive material” are nonstatutory when claimed as descriptive material per se. Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759. When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material, i.e., abstract ideas, stored in a computer-readable medium, in a computer, or on an electromagnetic carrier signal does not make it statutory. See Diehr, 450 U.S. at 185-86, 209 USPQ at 8 (noting that the claims for an algorithm in Benson were unpatentable as abstract ideas because “[t]he sole practical application of the algorithm was in connection with the

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programming of a general purpose computer.”) Such a result would exalt form over substance.

In re Saker, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978)...

Applicant is invited to view the following web site for the text of the new Interim  
Guideline guidelines of November 2005:

[http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101\\_20051026.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf)

*Response to Applicant's Arguments Regarding Non-statutory Subject Matter*

Applicant argues that the claims have been amended to includes “providing a list of genes whose associated values differ by an amount of statistical significance among the sets”.

Applicant states that the rejected independent claims “are believed to clearly set forth a process that causes a physical transformation outside the computer for which a practical application in the technical arts is disclosed in the specification”. Further, Applicant states that “the claim element “comparing the observed and expected values of the parameter to identify genes whose associated values differ by an amount of statistical significance among the sets” is a physical process that results in a physical transformation outside of the computer.

These arguments are not persuasive. As is stated above, the test for practical application is two-fold. No longer is practical application in the **technological arts** the standard. Rather, practical application refers to a claimed invention that “transforms” an article or physical object to a different state or thing or a claimed invention otherwise produces a useful, concrete, and tangible result, based upon various factors stated above. The instant claims do not meet either criteria and therefore are non-statutory. Further, there is no specific result of the claimed method

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steps and data transformation, even if it is listed, does not equate to a physical transformation outside of the computer.

Applicant argues the following:

“that in the case of *Arrhythmia Research Technology, Inc. v. Corazonix Corp.*, 22 USPQ 2d, 1033 at 103, referring to claim 1 (a method claim) of US Patent 4,422,459, “these claimed steps of...and ‘comparing’ are physical process steps that transform one physical, electrical signal into another. The view that ‘there is nothing necessarily physical about ‘signals is incorrect.’” The Federal Circuit then quoted in *re Taner*, 214 USPQ 678, 681 (CCPA 1982) with approval, where the court held that a method of seismic exploration including the mathematically described steps of “summing” and “simulating from” is statutory. Therefore, the claim element “comparing the observed and expected values of the parameter to identify genes whose associated values differ by an amount of statistical significance among the sets” in all of the rejected independent claims is a physical process that results in physical transformation outside the computer under the court holdings in these two cases, and under MPEP 2106, and renders that claims statutory”.

This is not persuasive. In the instant claims, the claims, as a whole, do not result in a physical transformation and as a whole do not constitute a practical application of an abstract idea (*State Street*, 149 F.3d at 1373, 47 USPQ2d at 1600). Thus data transformation is not necessarily a physical transformation, as it is the result as a whole, that is the focus. It is noted that the *Arrhythmia* case, for example, “constituted a practical application of an abstract idea because it corresponded to a useful, concrete , and tangible thing-the condition of the patient’s heart, which is not the case in the instant claimed invention.

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*Utility*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-22, 28-30, 33, 44, 46, 58, 60, 65, and 66 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, for the reasons set forth in the previous Office Action.

*Response to Applicants Arguments Regarding Utility*

Applicant has presented no arguments with regard to the Utility rejection set forth in the previous Office Action. The claims remains rejected.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22, 28-30, 33, 44, 46, 58, 60 are rejected under 35 U.S.C. 112, first paragraph, and new claims 65 and 66 are rejected as necessitated by amendment for failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the previous Office Action.



Applicant has removed expressions of “or protein” and “or proteins”, however, claim 1, line 4 still includes “protein”, as do amended claims 28, 46, 58, 60 and newly added claims 64 and 65.

### **Conclusion**

The outstanding rejections under 35 USC 112, 1<sup>st</sup> paragraph (new matter) have been withdrawn in view of Applicants amendments to the claims.

The outstanding rejection under 35 USC 102(e) has been withdrawn in view of Applicants arguments with regard to the scatter values defined by a standard deviation.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**NO CLAIMS ARE ALLOWED.**

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**Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

April 16, 2006  
Lori A. Clow, Ph.D.  
Art Unit 1631

*Lori A. Clow*

*Ardin H. Marschel 4/17/06*  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**